Medacta International

APR - 7 2009

510(k) Summary

Manufacturer: MEDACTA International SA
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Contact Person: Ms. Natalie J. Kennel
Consultant
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Date Prepared: February 20, 2009

DEVICE INFORMATION

Trade/Proprietary Name: Versafit Cup Double Mobility Family

Common Name: Total Joint Replacement
/Classification Name: Hip Joint, metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis

21 CFR 888.3353
Class II
Device Product Code: MEH

Predicate Devices: K070278 POLARCUP® Dual Mobility System
K072020 Restoration ™ ADM System

Product Description:
The Versafit Cup Double Mobility Acetabular Component is a two piece modular designed device consisting of the metal acetabular shell and a

mating polyethylene liner. The metal component is machined from stainless steel M30NW conforming to ISO 5832-9. The outer surface of the metallic cup has two types of coatings: Ti plasma spray and HA/Ti plasma spray. The polyethylene liner is a double mobility liner made of standard UHMWPE conforming to ISO 5834. The liner has a minimum thickness of 5 mm. The acetabular component is available in 10 sizes which accept both CoCrMo and MectaCer BIOLOX *forte* Ceramic ball heads with diameters of 22 and 28 mm.

The polyethylene double mobility liner is designed to articulate freely within the metal acetabular cup. The Versafit cup Double Mobility acetabular cup has a highly polished inner surface to facilitate this articulation.

The Versafit Cup Double Mobility Family is designed to be used with the Medacta Total Hip Prosthesis' Quadra S Stems and ball heads (K072857, K073337, K080885, K082792).

Indications for Use:
The Versafit Cup Double Mobility Acetabular Component Family is intended for cementless use in total hip arthroplasty and in primary or revision surgery.

The patient should be skeletally mature.

The patient's condition should be due to one or more of:

- Severely painful and/or disabled joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis,
- Congenital hip dysplasia
- Ankylosing spondylitis
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery, joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement where sufficient bone stock is present.
- Dislocation risks

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the Versafit Cup Double Mobility Family was conducted in accordance with various international standards and FDA guidance documents.

The Versafit Cup Double Mobility family was tested as part of design verification to written protocols with pre-defined acceptance criteria. The testing was conducted on the worst case component size and option/design. The testing met all acceptance criteria and verifies that the performance of

the Versafit Cup Double Mobility family is substantially equivalent to the predicate devices.

Conclusion:
The data and information provided in this submission support the conclusion that the Versafit Cup Double Mobility Family are substantially equivalent to its predicate devices, POLARCUP® Dual Mobility System and Restoration™ ADM System with respect to intended use, design, materials, and operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medacta International, SA
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Ms. Natalie J. Kennel
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San Diego, CA 92129

APR - 7 2009

Re: K083116
Trade/Device Name: Versafit Cup Double Mobility Family
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or non-porous uncemented prosthesis
Regulatory Class: II
Product Code: MEH
Dated: March 30, 2009
Received: April 3, 2009

Dear Ms. Kennel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

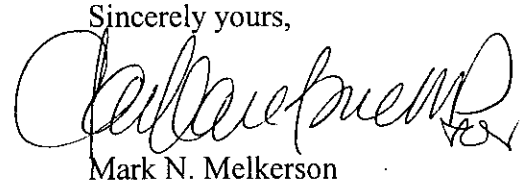
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083116

Device Name: Versafit Cup Double Mobility Family

Indications for Use:

The Versafit Cup Double Mobility Family is intended for cementless use in total hip arthroplasty and in primary or revision surgery.

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- Ankylosing spondylitis
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
- Dislocation risks

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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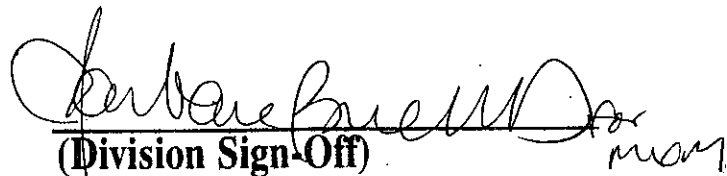
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083116